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L10: Entry 4 of 20 File: PGPB Feb 26, 2004

PGPUB-DOCUMENT-NUMBER: 20040038376
PGPUB-FILING-TYPE: new
DOCUMENT-IDENTIFIER: US 20040038376 A1

TITLE: Method for diagnosing atrophic gastritis

PUBLICATION-DATE: February 26, 2004

INVENTOR-INFORMATION:

NAME	CITY	STATE	COUNTRY
Suovaniemi, Osmo	Helsinki		FI
Harkonen, Matti	Espoo		FI
Tiusanen, Tapani	Vantaa		FI
Sipponen, Pentti	Espoo		FI

US-CL-CURRENT: 435/252.3

CLAIMS:

1. A method for assessing the condition of the gastric mucosa, especially for diagnosing mucosal gastric changes, such as atrophic gastritis, in a subject, by assaying the analytes pepsinogen I (PGI), gastrin and a marker for Helicobacter pylori infection, the method comprising measuring from a sample of said subject the pepsinogen I and gastrin concentration, and, in addition, determining the concentration or presence of a marker for Helicobacter pylori (Hp-marker), and entering the data so obtained for said analytes in a data processing means comprising an operating system, means for transceiving and processing data, said data processing means being adapted to perform the steps of comparing a measured concentration value for an analyte to a predetermined cut-off value for said analyte, to obtain a combination of comparison results which is specific for the subject tested, and generating information in response to the said combination of comparison results, and optionally other data entered.

2. The method according to claim 1, wherein the Helicobacter pylori marker is a Helicobacter pylori antibody, the concentration of which is measured from the sample.

3. The method according to claim 1, wherein the Helicobacter pylori marker is the Helicobacter pylori antigen, the presence of which is determined in the sample.

4. The method according to any one of the preceding claims, wherein the gastrin value measured is the gastrin-17 (G-17), especially the stimulated gastrin-17 value (G-17st), or both the gastrin-17 and the stimulated gastrin-17.

5. The method according to any one of the preceding claims, wherein, in addition, the concentration of the analyte pepsinogen II (PGII) is measured, and the ratio PGI/PGII is formed for comparison.

6. The method according to claim 2, wherein the analytes are measured from a body fluid, such as a serum, urine, saliva or lacrimal fluid sample, especially a serum sample.

7. The method according to any one of the preceding claims, wherein the data processing means comprise a display, and the information generated is displayed on the display.

8. The method according to any one of the preceding claims, wherein the information generated comprises diagnostic information relating to mucosal gastric changes.

9. The method according to any one of the preceding claims, wherein the information generated comprises suggestions for further treatment or for further investigations.

10. The method acording to any one of the preceding claims 8-9, wherein the information indicates the risk of peptic ulcer and/or cancer disease, and optionally of the associated risk factor.

11. The method according to any one of the preceding claims, wherein additional data relating to the age of the patient, reflux symptons, dyspepsia and/or anemia in the subject is entered as parameters.

12. The method according to any of the preceding claims, wherein the predetermined cut-off values for PGI and gastrin and optionally the Hp-marker and PGII are entered into the data processing means using means for data input and storing the data in storing means.

13. A kit comprising means for determining, from a sample, the pepsinogen I and/or gastrin concentration, and/or the concentration or presence of a Helicobacter pylori marker, as well as a computer program product embodied on a computer readable medium and comprising computer code means adapted to perform the steps of comparing a determined concentration value of an analyte to a predetermined cut-off value for said analyte, combining the results of comparison to a combination of comparison results, and providing information in response to said combination and optionally to other entered data, when run on a computer.

14. The kit according to claim 13, wherein the analytes to be determined and entered into the data processing system for comparison by the computer code means comprise a Hp-marker, PGI and gastrin, and wherein predetermined cut-off values for said analytes are stored on the computer readable medium containing the computer program and for use with the computer program, for use in a method according to any one of the preceding claims 1 to 12.

15. A computer program product embodied on a computer readable medium and comprising computer code means adapted to perform the steps of comparing measured concentrations of an analyte to a respective cut-off value for said analyte, combining the results of comparison to a combination of comparison results, and providing information in response to said combination and optionally to other entered data, when run on a computer.

16. The computer program product according to claim 15 wherein the analytes comprise a Hp-marker, PGI and gastrin, the product also comprising data for predetermined cut-off values for said analytes, for use in the method of any one of the preceding claims 1 to 12.

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L10: Entry 8 of 20 File: PGPB Nov 8, 2001

PGPUB-DOCUMENT-NUMBER: 20010039025
PGPUB-FILING-TYPE: new
DOCUMENT-IDENTIFIER: US 20010039025 A1

TITLE: Method for screening the risk of gastric cancer

PUBLICATION-DATE: November 8, 2001

INVENTOR-INFORMATION:

NAME	CITY	STATE	COUNTRY
Harkonen, Matti	Espoo		FI

US-CL-CURRENT: 435/7.32; 435/7.23

CLAIMS:

1. A method for screening for atrophy of the corpus or antrum area of the stomach from blood serum, such atrophy correlating with increased risk of gastric cancer, wherein said method comprises determining quantitatively the pepsinogen I and gastrin-17 concentrations from a serum sample and comparing the values obtained to a cut-off value and reference value for pepsinogen I and gastrin-17, whereby a pepsinogen I concentration in the serum sample below the cut-off value selected from a range of approximately 20-30 .mu.g/l in combination with a gastrin-17 above the upper reference limit of 2-25 pmol/l is taken to be indicative of atrophy of the corpus area of the stomach, and a pepsinogen I concentration above said cut-off value in combination with a gastrin-17 concentration in the serum sample below the cut-off value selected from a range of approximately 0.1-2 pmol/l is taken to be indicative of atrophy of the antrum area of the stomach.

2. A method for screening for atrophy of the mucosa of the whole stomach from blood serum, such atrophy correlating with increased risk of gastric cancer which comprises determining quantitatively the pepsinogen I and gastrin-17 concentrations from a serum sample and comparing the values obtained to a cut-off value of 20-30 .mu.g/l for pepsinogen I and a reference value of 2-25 pmol/l for gastrin-17 whereby a pepsinogen I concentration in the serum sample below the cut-off value for pepsinogen I and a gastrin-17 concentration in the serum sample at [the lower limit of] the reference value for gastrin-17 is taken to be indicative of atrophy of the mucosa of the whole stomach.

3. The method according to claim 1 or 2, wherein the serum gastrin-17 concentration is also measured using the protein stimulation test by measuring the said concentration at the base line situation and after a protein rich standard meal.

4. The method according to claim 1 or 2, wherein the methods for detection of pepsinogen-1 and gastrin-17 are selected from the group consisting of absorbance, fluorescence and luminescence assay methods.

5. The method according to claim 1 or 2, wherein the determination of the pepsinogen I concentration is performed using polyclonal or monoclonal antibodies which specifically bind to pepsinogen I.

6. The method according to claim 1 or 2, wherein the determination of the gastrin-17 concentration is performed using polyclonal or monoclonal antibodies which specifically bind to gastrin-17.

7. The method according to claim 6, wherein a polyclonal antibody to gastrin-17 is obtained by immunizing an animal with the gastrin fragment 1-13, {Leu.sup.15}-gastrin-17 or using a gastrin-17 antigen isolated from the stomach of an animal [such as a pig].

8. The method according to claim 6, wherein said monoclonal antibodies are mouse monoclonal antibodies which specifically bind to {Leu.sup.15}-gastrin-17 antigen.

9. The method according to claim 1 or 2, wherein the method is performed in combination with a Helicobacter pylori antibody determination.

10. A method for screening for atrophy of the corpus or antrum area of the stomach from blood serum, such atrophy correlating with increased risk of gastric cancer, wherein said method comprises determining quantitatively the pepsinogen I and gastrin-17 concentrations from a serum sample and comparing the values obtained to a cut-off value and reference value for pepsinogen I and gastrin-17, whereby a pepsinogen I concentration in the serum sample below the cut-off in combination with a gastrin-17 above the upper reference limit is taken to be indicative of atrophy of the corpus area of the stomach, and a pepsinogen I concentration above said cut-off value in combination with a gastrin-17 concentration in the serum sample below the cut-off value is taken to be indicative of atrophy of the antrum area of the stomach.

11. A method for screening for atrophy of the mucosa of the whole stomach from blood serum, such atrophy correlating with increased risk of gastric cancer which comprises determining quantitatively the pepsinogen I and gastrin-17 concentrations from a serum sample and comparing the values obtained to a cut-off value for pepsinogen I and a reference value for gastrin-17, whereby a pepsinogen I concentration in the serum sample below the cut-off value and a gastrin-17 concentration in the serum sample at the reference value for gastrin-17 is taken to be indicative of atrophy of the mucosa of the whole stomach.

12. The method according to claim 10 or 11, wherein the serum gastrin-17 concentration is also measured using the protein stimulation test by measuring the said concentration at the base line situation and after a protein rich standard meal.

13. The method according to claim 10 or 11, wherein the methods for detection of pepsinogen-1 and gastrin-17 are selected from the group consisting of absorbance, fluorescence and luminescence assay methods.

14. The method according to claim 10 or 11, wherein the determination of the pepsinogen I concentration is performed using polyclonal or monoclonal antibodies which specifically bind to pepsinogen I.

15. The method according to claim 10 or 11, wherein the determination of the gastrin-17 concentration is performed using polyclonal or monoclonal antibodies which specifically bind to gastrin-17.

16. The method according to claim 15, wherein a polyclonal antibody to gastrin-17 is obtained by immunizing an animal with the gastrin fragment 1-13, {Leu.sup.15}-gastrin-17 or using a gastrin-17 antigen isolated from the stomach of an animal.

17. The method according to claim 15, wherein said monoclonal antibodies are mouse monoclonal antibodies which specifically bind to {Leu.sup.15}-gastrin-17 antigen.

18. The method according to claim 10 or 11, wherein the method is performed in combination with a Helicobacter pylori antibody determination.

19. A method for screening for atrophy of the corpus and antrum area of the stomach from blood serum, such atrophy correlating with increased risk of gastric cancer, wherein said method consists of determining quantitatively the pepsinogen I and gastric-17 concentrations from a serum sample and comparing the values obtained to a cut-off value and reference value for pepsinogen I and gastrin-17, whereby a pepsinogen I concentration in the serum sample below the cut-off value of 30 .mu.g/l in combination with a gastrin-17 above the upper reference limit of 2 pmol/l is taken to be indicative of atrophy of the corpus area of the stomach, and a

pepsinogen I ,concentration above said cut-off value in combination with a gastrin-17 concentration in the serum sample below the cut-off value of 2 pmol/l is taken to be indicative of atrophy of the antrum area of the stomach.

20. A method for screening for atrophy of the mucosa of the whole stomach from blood serum, such atrophy correlating with increased risk of gastric cancer which comprises determining quantitatively the pepsinogen I and gastrin-17 concentrations from a serum sample and comparing the values obtained to a cut-off value selected from the range of approximately 20-30 .mu.g/l for pepsinogen I and a reference value of 2-25 pmol/l for gastrin-17, whereby a pepsinogen I concentration in the serum sample below the cut-off value and a gastrin-17 concentration in the serum sample at the lower limit of the reference values for gastrin-17 is taken to be indicative of atrophy of the mucosa of the whole stomach.

21. The method according to claim 20, wherein the serum gastrin-17 concentration is also measured using the protein stimulation test by measuring the said concentration at the base line situation and after a protein rich standard meal.

22. The method according to claim 20, wherein the methods for detection of pepsinogen-1 and gastrin-17 are selected from the group consisting of absorbance, fluorescence and luminescence assay methods.

23. The method according to claim 20, wherein the determination of the pepsinogen I concentration is performed using polyclonal or monoclonal antibodies which specifically bind to pepsinogen I.

24. The method according to claim 20, wherein the determination of the gastrin-17 concentration is performed using polyclonal or monoclonal antibodies which specifically bind to gastrin-17.

25. The method according to claim 24, wherein a polyclonal antibody to gastrin-17 is obtained by immunizing an animal with the gastrin fragment 1-13, {Leu.sup.15}-gastrin-17 or using a gastrin-17 antigen isolated from the stomach of an animal.

26. The method according to claim 25, wherein said monoclonal antibodies are mouse monoclonal antibodies which specifically bind to {Leu.sup.15}-gastrin-17 antigen.

27. The method according to claim 20, wherein the method is performed in combination with a Helicobacter pylori antibody determination.

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L10: Entry 9 of 20 File: USPT Mar 29, 2005

US-PAT-NO: 6872543
DOCUMENT-IDENTIFIER: US 6872543 B1

TITLE: Method for assessing the risk of peptic ulcer, comprising the steps of determining quantitatively the concentrations of pepsinogen I (PGI) and gastrin-17 in a serum sample

DATE-ISSUED: March 29, 2005

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Sipponen; Pentti	Espoo			FI
Harkonen; Matti	Espoo			FI
Suovaniemi; Osmo	Helsinki			FI
Forsblom; Erik	Espoo			FI

US-CL-CURRENT: 435/7.32; 435/252.3, 435/4, 435/6, 435/7.1, 435/7.23, 435/7.4, 435/7.7, 435/7.72, 435/7.91, 530/350, 530/387.1, 530/388.1, 530/388.4, 530/388.7

CLAIMS:

What is claimed is:

1. A method for assessing the risk of duodenal ulcer comprising a) obtaining a serum sample from a patient; b) quantitatively measuring the pepsinogen I from said serum sample using an immunoassay and comparing the value obtained to a reference range of 25-125 .mu.g/l for pepsinogen I; and c) quantitatively measuring the gastrin-17 from said serum sample using an immunoassay and comparing the value obtained to a reference range of 2-25 pmol/l,

whereby a pepsinogen I concentration in said serum sample above the upper limit of the pepsingogen I reference range and a gastrin-17 concentration above the upper limit of the gastrin-17 reference range is indicative of an increased risk of duodenal ulcer.

2. A method for assessing the risk of gastric ulcer comprising a. obtaining a serum sample from a patient; b. quantitatively measuring the pepsinogen I from said serum sample using an immunoassay and comparing the value obtained to a method-specific reference range of 25-125 .mu.g/l for pepsinogen I; and c. quantitatively measuring the gastrin-17 from said serum sample using an immunoassay and comparing the value obtained to a gastrin-17 cut - off value of 0.1-2 pmol/l, which overlaps the lower end of the reference range of 2-25 pmol/l for gastrin-17,

whereby a pepsinogen I concentration in said serum sample above the upper limit of the pepsinogen I reference range and a gastrin-17 concentration within the gastrin-17 reference range or below the gastrin-17 cut-off value is indicative of an increased risk of gastric ulcer.

3. The method according to the claim 1 or 2, further comprising conducting an immunoassay to detect the presence of Helicobacter pylori antibodies.

4. The method according to claim 1 or 2, further comprising a protein stimulation test that measures serum gastrin-17 concentration after fasting and then after a protein rich

standard meal.

5. The method according to claim 4, wherein no change in the serum gastrin-17 concentration after a protein rich meal as compared with the value after fasting is indicative of a risk of gastric ulcer.

6. The method according to the claim 1 or 2, wherein said pepsinogen I or gastrin-17 immunoassay is conducted on a plastic, glass or cellulose support.

7. The method according to the claim 6, wherein said plastic, glass or cellulose support is a microplate.

8. The method according to claim 1 or 2, wherein said immunoassay is conducted with an enzyme labeled antibody and absorbance, fluorescence or luminescence is measured.

9. The method according to claim 1 or 2, wherein said pepsinogen I immunoassay is performed using a polyclonal or monoclonal antibody, which specifically binds to said pepsinogen I.

10. The method according to claim 1 or 2, wherein said gastrin-17 immunoassay is performed using a polyclonal or monoclonal antibody, which specifically binds to said gaatrin-17.

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L10: Entry 12 of 20 File: USPT Feb 24, 2004

US-PAT-NO: 6696262
DOCUMENT-IDENTIFIER: US 6696262 B2

TITLE: Method for screening the risk of gastric cancer

DATE-ISSUED: February 24, 2004

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Harkonen; Matti	Espoo			FI

US-CL-CURRENT: 435/7.32; 435/7.1, 435/7.23, 435/7.4, 435/7.7, 435/7.72, 435/7.91

CLAIMS:

What is claimed is:

1. A method for screening for atrophy of the corpus of the stomach from blood serum, such atrophy correlating with increased risk of gastric cancer, said method comprising: a) obtaining a serum sample from a patient; b) quantitatively measuring the pepsinogen-I from said serum sample using an immunoassay and comparing the value obtained to a cut-off value for pepsinogen-I selected from a range of approximately 20-30 .mu.g/l, which overlaps the lower end of the reference range of approximately 25-120 .mu.g/l; and c) quantitatively measuring the gastrin-17 concentration from said serum sample by immunoassay and comparing the values obtained to a reference range of approximately 2-25 pmol/l for gastrin-17,

whereby a pepsinogen-I concentration in said serum sample below the cut-off value in combination with a gastrin-17 above the upper reference limit is indicative of atrophy of the corpus area of the stomach.

2. A method for screening for atrophy of the mucosa of the whole stomach from blood serum, such atrophy correlating with increased risk of gastric cancer, which comprises: a) obtaining a serum sample from a patient, b) quantitatively measuring the pepsinogen-I from said serum sample using an immunoassay and comparing the value obtained to a cut-off value for pepsinogen-I selected from a range of approximately 20-30 .mu.g/l, which overlaps the lower end of the reference range of approximately 25-120 .mu.g/l; and c) quantitatively measuring the gastrin-17 concentration from said serum sample and comparing the value obtained to a reference range of 2-25 pmol/l for gastrin-17,

whereby a pepsinogen-I concentration in said serum sample below the pepsinogen-1 cut-off value and a gastrin-17 concentration in said serum sample within the reference range for gastrin-17 is indicative of atrophy of the mucosa of the whole stomach.

3. The method according to claim 1 or 2, further comprising a protein stimulation test that measures serum gastrin-17 concentration after fasting and then after a protein rich standard meal.

4. The method according to claim 1 or 2, wherein said immunoassay is conducted with an enzyme labeled antibody and a chromogenic, fluorescent or luminescent substrate, and absorbance, fluorescence or luminescence is measured.

5. The method according to claim 1 or 2, wherein said pepsinogen-I immunoassay is performed using polyclonal or monoclonal antibodies which specifically bind to said pepsinogen-I.

6. The method according to claim 1 or 2, wherein said gastrin-17 immunoassay is performed using polyclonal or monoclonal antibodies which specifically bind to said gastrin-17.

7. The method according to claim 6, wherein a polyclonal antibody to gastrin-17 is obtained by immunizing an animal with the gastrin fragment 1-13, {Leu.sup.15 }-gastrin-17 or using a gastrin-17 antigen isolated from the stomach of an animal.

8. The method according to claim 6, wherein said monoclonal antibodies are mouse monoclonal antibodies which specifically bind to {Leu.sup.15 }-gastrin-17 antigen.

9. The method according to claim 1 or 2, further comprising an immunoassay to detect the presence of Helicobacter pylori antibodies.

10. A method for screening for atrophy of the antrum area of the stomach from blood serum such atrophy correlating with increased risk of gastric cancer, which comprises: a) obtaining a blood serum sample from a patient b) quantitatively measuring the pepsinogen-I concentrations using an immunoassay and comparing the value obtained to a cut-off value for pepsinogen-I selected from the range of approximately 20-30 .mu.g/l, which overlaps the lower end of the reference range of approximately 25-120 g/l; and c) quantitatively measuring the gastrin-17 concentration from said serum sample by immunoassay and comparing it to a cut-off value for gastrin-17 selected from a range of approximately 0.1-2 pmol/l, which is below the reference range of approximately 2-25 pmol/l

whereby a pepsinogen I concentration above said cut-off value in combination with a gastrin-17 concentration in said sample below said cut-off value is indicative of atrophy of the antrum area of the stomach.

11. The method according to claim 10, further comprising a protein stimulation test that measures serum gastrin-17 concentrations after fasting and then after a protein rich standard meal.

12. The method according to claim 10, wherein said immunoassay is conducted with an enzyme labeled antibody and a chromogenic, fluorescent or luminescent substrate, and absorbance, fluorescence or luminescence is measured.

13. The method according to claim 10, wherein said immunoassay for said pepsinogen-I concentration is performed using polyclonal or monoclonal antibodies which specifically bind to pepsinogen-I.

14. The method according to claim 10, further comprising an immunoassay to detect the presence of Helicobacter pylori antibodies.

15. The method according to claim 10, wherein said immunoassay for said gastrin-17 concentration is performed using polyclonal or monoclonal antibodies which specifically bind to gastrin-17.

16. The method according to claim 15, wherein a polyclonal antibody to gastrin-17 is obtained by immunizing an animal with the gastrin fragment 1-13, {Leu.sup.15 }-gastrin-17 or using a gastrin-17 antigen isolated from the stomach of an animal.

17. The method according to claim 16, wherein said monoclonal antibodies are mouse monoclonal antibodies which specifically bind to {Leu.sup.15 }-gastrin-17 antigen.

18. A method for screening for atrophy of the corpus of the stomach from blood, serum or plasma, such atrophy correlating with increased risk of gastric cancer, said method

comprising: a) obtaining a blood, serum or plasma sample from a patient; b) quantitatively measuring the pepsinogen-I from said sample using an immunoassay and comparing the value obtained to a cut-off value for pepsinogen-I selected from a range of approximately 20-30 .mu.g/l, which overlaps the lower end of the pepsinogen-I reference range of approximately 25-120 .mu.g/l; and c) quantitatively measuring the gastrin-17 concentration from serum sample by immunoassay and comparing the values obtained to a reference range of approximately of 2-25 pmol/l for gastrin-17, whereby a pepsinogen-I concentration in said sample below the pepsinogen-I cut-off value in combination with a gastrin-17 above the upper gastrin-17 reference limit is indicative of atrophy of the corpus area of the stomach.

19. A method for screening for atrophy of the mucosa of the whole stomach from blood, serum or plasma, such atrophy correlating with increased risk of gastric cancer which comprises: a) obtaining a blood, serum or plasma sample from a patient, b) quantitatively measuring the pepsinogen-I from said sample using an immunoassay and comparing the value obtained to a cut-off value for pepsinogen-I selected from a range of approximately 20-30 .mu.g/l, which overlaps the lower end of the reference range of approximately 25-120 .mu.g/l; and c) quantitatively measuring the gastrin-17 concentration from said sample and comparing the value obtained to a reference range of 2-25 pmol/l for gastrin-17, whereby a pepsinogen-I concentration in said sample below the pepsinogen-1 cut-off value and a gastrin-17 concentration in said serum sample within the reference range for gastrin-17 is indicative of atrophy of the mucosa of the whole stomach.

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L10: Entry 14 of 20 File: USPT Aug 27, 2002

DOCUMENT-IDENTIFIER: US 6441131 B1
TITLE: Peptides, method for assaying human pepsinogen II or human pepsin II, and assaying kit

Abstract Text (3):
A compound of the formula (I) is a specific substrate for human pepsin II, so it can be used for assaying human pepsin II or human pepsinogen II and it is useful for diagnosis of gastric diseases such as gastric cancer and gastric ulcer.

Brief Summary Text (2):
The present invention relates to a method for assaying human pepsin II or human pepsinogen II in the human body fluid (such as gastric juice, blood, urine etc.) as diagnostic marker of gastric diseases such as gastric cancer, gastric ulcer etc. and a peptide used as a substrate in such a method.

Brief Summary Text (5):
or an acid addition salt thereof and, 2) a method for assaying human pepsinogen II or human pepsin II which is characterized by digesting a peptide of the formula (I) (wherein all the symbols are as defined hereinbefore.) described in the said 1) or an acid addition salt thereof by human pepsin II which is obtained by activation of human pepsinogen II in a sample or human pepsin II in a sample to obtain an amino acid derivative of the formula (II) ##STR3##

Brief Summary Text (6):
(wherein all the symbols are as defined hereinbefore.), digesting the obtained amino acid derivative by aminopeptidase to obtain an aniline, aminocoumarine or aminonaphthalene derivative of the formula Z--H and then detecting the obtained aniline, aminocoumarine or aminonaphthalene derivative and 3) a kit for assaying human pepsinogen II or human pepsin II which is characterized by comprising a peptide of the formula (I) (wherein all the symbols are as defined hereinbefore.) described in the said 1) or an acid addition salt thereof as a substrate and an aminopeptidase.

Brief Summary Text (8):
It is known that the pepsinogen secretion is parallel to gastric acid secretion and that human serum or urine pepsinogen levels are also parallel to gastric pepsinogen secretion. The above pepsinogen exists as pepsinogen in the body fluid such as blood or urine except for gastric juice, on the other hand, it exists as pepsin in gastric juice.

Brief Summary Text (9):
It is said that human blood or urine pepsinogen I level of the patient with atrophic gastritis decreases and that human blood or urine pepsinogen I and pepsinogen II levels increase in case of gastric ulcer (Japanese Patent Application Kokai Hei 7-304800). In addition, it is said that both pepsinogen I level and pepsinogen II/I ratio decrease in the patient with gastric cancer (Jpn. J. Cancer Res., 80, 111-114 (1989)).

Brief Summary Text (10):
Further, an attention is paid to serum pepsinogen II level and pepsinogen I/II ratio as markers of therapy for helicobacter pylori gastritis. That is to say, it is said that serum pepsinogen II level decreases significantly and pepsinogen I/II ratio increases significantly in a successful group consisting of patients in whom therapy resulted in eradication of the bacteria to compare with an unsuccessful group consisting of patients who remained infected (Prog. Med., 15, 1862-1868 (1995)).

Brief Summary Text (11):
Therefor, assaying the level of human pepsinogen II in human blood or urine may be useful for

diagnosis at early stage of diseases such as gastric cancer, gastric ulcer and duodenal ulcer etc.

Brief Summary Text (12):
As for a method for assaying human pepsin which was obtained by activation of human pepsinogen, a method using human serum protein etc. in urine and serum based on its digesting activity has been known (Clin. Chem., 15, 1, 42-55 (1969)). The significance of clinical trial using such a method has been discussed, but it requires a long time. In addition, its accuracy was not good, so such a method has been of no practical use. Further, the results means the activity to digest protein, so it was reflected on the total activities of both pepsin I and pepsin II. Therefore it is impossible to determine the human serum pepsinogen II specifically.

Brief Summary Text (13):
Recently, a method for assaying human pepsinogen in urine (uropepsin) indirectly, based on inactivation of an acidic enzyme by activated pepsin was proposed (Japanese Patent Application Kokai Hei 7-155198). But the substrate used in this method did not show the specificity for pepsin II. It is said that the pepsinogen in urine is pepsinogen I. But, pepsin II may be also secreted in urine in some body condition, so it is difficult to determine the accurate level of pepsin II. It is impossible to assay the level of pepsinogen II in human serum specifically.

Brief Summary Text (14):
As for a method for assaying pepsinogen II, radio immunoassay (Kaku-igaku (in Japanese), Vol. 26, No. 9, 1217-1221 (1989)) and enzyme immunoassay (Japanese Patent Application Kokai Hei 7-304800) using a specific anti-body have been practical use, but these methods cause a radioactive pollution and require a long time and complicated procedure for assaying.

Brief Summary Text (47):
The present inventors have been studying to dissolve these problems of the related arts and to find a substrate which is high-sensitive (being high rate of enzyme reaction i.e., digesting a substrate by human pepsin II at a high rate and/or being able to produce efficient coloring) and specific for human pepsin II, and then have succeeded in synthesizing a substrate (peptide) which is sensitive and specific for human pepsin II. By using this substrate, it become to possible to determine pepsin II for short time to compare with the method of related arts and to determine pepsinogen II and pepsin II using automated clinical analyzer.

Brief Summary Text (49):
(wherein all the symbols are as defined hereinbefore.), or acid addition salt thereof, 2) a method for assaying human pepsinogen II or human pepsin II characterized by digesting a peptide of the formula (I) described in the above 1) (wherein all the symbols are as defined hereinbefore.), or an acid addition salt thereof, by human pepsin II which is obtained by activation of human pepsinogen II in a sample or human pepsin II in a sample to obtain an amino acid derivative of the formula (II) ##STR6##

Brief Summary Text (50):
(wherein all the symbols are as defined hereinbefore.), digesting the obtained amino acid derivative by aminopeptidase to obtain an aniline, aminocoumarine or aminonaphthalene derivative of the formula Z--H and then detecting the obtained aniline, aminocoumarine or aminonaphthalene derivative, 3) a kit for assaying human pepsinogen II or human pepsin II which is characterized by comprising a peptide of the formula (I) described in the above 1), or an acid addition salt thereof as a substrate and aminopeptidase.

Drawing Description Text (2):
FIG. 1 shows calibration curve between pepsinogen II level (ng/ml) and the plotted increase of absorbance in Example 4.

Drawing Description Text (3):
FIG. 2 shows correlation between a conventional method for assaying serum pepsinogen II (RIA) using a kit for assaying pepsinogen II (marketed from Dinabott Co), and a method for assaying of the present invention. The values on the abscissa and ordinate indicate the detected value (ng/ml) determined by RIA method and the increase of absorbance determined by the method of the present invention, respectively.

Drawing Description Text (4):
FIG. 3 shows calibration curve between pepsinogen II level (ng/ml) and the plotted increase of

absorbance in Example 6.

Drawing Description Text (5):
FIG. 4 shows correlation between a conventional method for assaying serum pepsinogen II (RIA) using a kit for assaying pepsinogen II (marketed from Dinabott Co), and a method for assaying of the present invention. The values on the abscissa and ordinate indicate the detected value (ng/ml) determined by RIA method and the increase of absorbance determined by the method of the present invention, respectively.

Detailed Description Text (2):
A sample as an objet in the present invention means any sample to be determined the concentration of human pepsinogen II and activity of human pepsin II. For example, such a sample includes human body fluid (such as gastric juice, blood or urine etc.). The above pepsinogen II (pepsin II) exists as form of pepsinogen II in the body fluid such as blood or urine except for gastric juice, on the other hand, it exists as form of pepsin II in gastric juice.

Detailed Description Text (47):
As for a sample, in case of body fluid except for gastric juice such as blood, urine etc., human pepsinogen II is activated to human pepsin II in the First reaction, and the obtained human pepsin II recognizes and digests a peptide of the formula (I) (wherein all the symbols are as defined hereinbefore.) or an acid addition salt thereof as a substrate, specifically. This activation of human pepsinogen II may be carried out, for example, under an acidic condition in combination with digesting a substrate at the same time or separately. As for this acidic condition, pH1.0.about.6.0 is preferable. A buffer includes tartaric acid, glycine, citric acid, oxalic acid, formic acid or and acetic acid buffer preferably. An amino acid derivative of the formula (II) ##STR15##

Detailed Description Text (48):
(wherein all the symbols are as defined hereinbefore.) which is released after digesting reaction is digested by aminopeptidase (for example, aminopeptidase M derived from pig kidney) at pH6.about.9 in Second reaction to release an aniline, aminocoumarine or aminonaphthalene derivative of the formula Z--H. It is possible to assay human pepsinogen II in a sample by detecting the obtained aniline, aminocoumarine or aminonaphthalene derivative.

Detailed Description Text (53):
A peptide of the formula (i) or an acid addition salt thereof of the present invention is a substrate possessing the specificity for human pepsin II and high sensitivity (digesting a substrate by pepsin II at a high rate and/or being able to produce efficient coloring). Therefore, a method for assaying human pepsin II or human pepsinogen II by using a peptide or an acid addition salt thereof of the present invention is useful for diagnosis of gastric diseases such as gastric cancer, gastric ulcer etc. and contributes to the clinical field.

Detailed Description Text (83):
Assaying Human Pepsinogen II by the Method of the Present Invention (Calibration Curve)

Detailed Description Text (89):
Purified human pepsinogen II

Detailed Description Text (92):
The correlation between the concentration of pepsinogen II and increase in absorbance is shown in FIG. 1.

Detailed Description Text (93):
As is shown clearly from FIG. 1, calibration curve obtained from each pepsinogen II level (ng/ml) and the plotted increase in absorbance passes through zero point showing a good linearity and quantatativeness.

Detailed Description Text (95):
Assaying Human Pepsinogen II in Blood by the Method of the Present Invention (The Correlation of the Method Between the Present Invention and RIA)

Detailed Description Text (103):
The assaying serum pepsinogen II was carried out by a marketed kit for assaying pepsinogen II

(Dinabott Co) (RIA method) according to the procedure described in explanation. The correlation of the results of the method between the present invention and RIA is shown in FIG. 2.

Detailed Description Text (104):
As is shown clearly from FIG. 2, we understand that there is a good correlation of the results of the method between the present invention and RIA, and that serum pepsinogen II was determined correctly by the method of the present invention.

Detailed Description Text (106):
Assaying Human Pepsinogen II by the Method of the Present Invention

Detailed Description Text (112):
Purified human pepsinogen II

Detailed Description Text (115):
The correlation between the concentration of pepsinogen II and increase in absorbance is shown in FIG. 3.

Detailed Description Text (116):
As is shown clearly from FIG. 3, calibration curve obtained from each pepsinogen II level (ng/ml) and the plotted increase in absorbance passes through zero point showing a good linearity and quantatativeness.

Detailed Description Text (118):
Assaying Human Pepsinogen II by the Method of the Present Invention (The Correlation of the Method Between the Present Invention and RIA)

Detailed Description Text (126):
The assaying serum pepsinogen II was carried out by the same procedure as Example 5. The correlation of the results of the method between the present invention and RIA is shown in FIG. 4.

Detailed Description Text (127):
As is shown clearly from FIG. 4, we understand that there is a good correlation of the results of the method between the present invention and RIA, and that serum pepsinogen II was determined correctly by the method of the present invention.

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Detailed Description Paragraph Table (5):

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Detailed Description Paragraph Table (6):

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Detailed Description Paragraph Table (7):
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CLAIMS:

8. A method for assaying human pepsinogen II or human pepsin II characterized by digesting a peptide of the formula (I) depicted in claim 1, wherein all the symbols are as defined in claim 1, or an acid addition salt thereof, by human pepsin II which is obtained by activation of human pepsinogen II in a sample or human pepsin II in a sample to obtain an amino acid derivative of the formula (II) ##STR25## wherein all the symbols are as defined in claim 1, digesting the obtained amino acid derivative of the formula (II) by aminopeptidase to obtain an aniline, aminocoumarine or aminonaphthalene derivative of the formula Z--H, and then detecting the obtained aniline, aminocoumarine or aminonaphthalene derivative.

10. A kit for assaying human pepsinogen II or human pepsin II which is characterized by comprising a peptide of the formula (I) as depicted in claim 1 (wherein all the symbols are as defined in claim 1) or an acid addition salt thereof as a substrate and aminopeptidase.

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L10: Entry 17 of 20 File: EPAB Jul 11, 2002

PUB-NO: WO002054084A1
DOCUMENT-IDENTIFIER: WO 2054084 A1
TITLE: A METHOD FOR DIAGNOSING ATROPHIC GASTRITIS

PUBN-DATE: July 11, 2002

INVENTOR-INFORMATION:

NAME	COUNTRY
SUOVANIEMI, OSMO	FI
HAERKOENEN, MATTI	FI
TIUSANEN, TAPANI	FI
SIPPONEN, PENTTI	FI

INT-CL (IPC): G01 N 33/74; G01 N 33/573
EUR-CL (EPC): G01N033/569; G01N033/573, G01N033/68 , G01N033/74

ABSTRACT:

CHG DATE=20031129 STATUS=O>The invention concerns a method for assessing the condition of the gastric mucosa, especially for diagnosing mucosal gastric changes, such as atrophic gastritis, in a subject, by assaying the analytes pepsinogen I (PGI), gastrin and a marker for Helicobacter pylori infection, the method comprising - measuring from a sample of said subject the pepsinogen I and gastrin concentration, and, in addition, determining the concentration or presence of a marker for Helicobacter pylori (Hp-marker), and- entering the data so obtained for said analytes in a data processing means comprising an operating system, means for transceiving and processing data, said data processing means being adapted to perform the steps of - comparing a measured concentration value for an analyte to a predetermined cut-off value for said analyte, to obtain a combination of comparison results which is specific for the subject tested, and generating information in response to the said combination of comparison results, and optionally other data entered.The invention is also directed to a kit and to computer program product especially for use in the method according to the invention.

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L10: Entry 20 of 20 File: DWPI Oct 20, 2005

DERWENT-ACC-NO: 2002-557755
DERWENT-WEEK: 200569

TITLE: Assessing gastric mucosa in a subject, by assaying pepsinogen I, gastrin, and marker for Helicobacter pylori infection and comparing measured concentration of an analyte to predetermined cut-off value of the analyte

INVENTOR: HARKONEN, M; SIPPONEN, P ; SUOVANIEMI, O ; TIUSANEN, T ; HAERKOENEN, M

PRIORITY-DATA: 2001FI-0000019 (January 5, 2001)

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PATENT-FAMILY:

PUB-NO	PUB-DATE	LANGUAGE	PAGES	MAIN-IPC
RU 2262706 C2	October 20, 2005		000	G01N033/74
WO 200254084 A1	July 11, 2002	E	031	G01N033/74
FI 200100019 A	July 6, 2002		000	G01N000/00
EP 1348129 A1	October 1, 2003	E	000	G01N033/74
US 20040038376 A1	February 26, 2004		000	C12N001/20
AU 2002226434 A1	July 16, 2002		000	G01N033/74
CN 1484765 A	March 24, 2004		000	G01N033/74
JP 2004517322 W	June 10, 2004		049	G01N033/53

INT-CL (IPC): C12 N 1/20; G01 N 0/00; G01 N 33/53; G01 N 33/569; G01 N 33/573; G01 N 33/68; G01 N 33/74

ABSTRACTED-PUB-NO: WO 200254084A
BASIC-ABSTRACT:

NOVELTY - Assessing (M) the condition of gastric mucosa, especially for diagnosing mucosal gastric changes such as atrophic gastritis in a subject, involves assaying the analytes pepsinogen I (PGI), gastrin, and marker for Helicobacter pylori infection, and entering the obtained data for analytes to obtain a combination of comparison results specific for the subject tested, and generating the information.

DETAILED DESCRIPTION - Assessing (M) the condition of the gastric mucosa, especially for diagnosing mucosal gastric changes, such as atrophic gastritis, in a subject, by assaying the analytes pepsinogen I (PGI), gastrin, and a marker for Helicobacter pylori infection, involves measuring from a sample of the subject the pepsinogen I and gastrin concentration, and, in addition, determining the concentration or presence of a marker for H.pylori (Hp-marker), and entering the data so obtained for the analytes in a data processing unit comprising an operating system, unit for transceiving and processing data, the data processing unit is adapted to perform the steps of comparing a measured concentration value for an analyte to a predetermined cutoff value for the analyte, to obtain a combination of comparison results which

is specific for the subject tested, and generating information in response to the combination of comparison results, and optionally other data entered.

INDEPENDENT CLAIMS are also included for the following:

(1) a kit (I) comprising unit for determining, from a sample, the PGI and/or gastrin concentration, and/or the concentration or presence of Hp-marker, as well as a computer program product embodied on a computer readable medium and comprising computer code unit adapted to perform the steps of comparing a determined concentration value of an analyte to a predetermined cut-off value for the analyte, combining the results of comparison to a combination of comparison results, and providing information in response to the combination and optionally to other entered data, when run on a computer; and

(2) a computer program product (II) embodied on a computer readable medium and comprising computer code unit adapted to perform the steps of comparing measured concentration value of an analyte to a respective cut-off value for the analyte, combining the results of comparison to a combination of comparison results, and providing information in response to the combination and optionally to other entered data, when run on a computer.

USE - (M) is useful for assessing the condition of gastric mucosa, especially for diagnosing mucosal gastric changes such as atrophic gastritis in a subject, where the analytes are measured from a body fluid, such as serum, urine, saliva, or lacrimal fluid sample, especially a serum sample. The information indicates the risk of peptic ulcer and/or cancer disease, and optionally of the associated risk factor (claimed).

DESCRIPTION OF DRAWING(S) - The figure shows a schematic representation of assessing a condition of gastric mucosa, such as atrophic gastritis in a subject, by assaying PGI, gastrin, and Hp-marker.

ABSTRACTED-PUB-NO: WO 200254084A
EQUIVALENT-ABSTRACTS:

CHOSEN-DRAWING: Dwg.1/1

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